IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)	**CASE NO. 1:09-MD-2084-TWT** **END-PAYOR CLASS ACTIONS**
FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, **Plaintiff,** **v.** **UNIMED PHARMACEUTICALS, INC. et al.,** **Defendants.**	**CASE NO. 1:09-CV-2914-TWT**
GEORGE STEVEN LEGRAND, **Plaintiff,** **v.** **UNIMED PHARMACEUTICALS, INC. et al.,**	**CASE NO. 1:10-CV-2883-TWT**
HEALTH NET, INC., **Plaintiff,** **v.** **UNIMED PHARMACEUTICALS, INC. et al.,** **Defendants.**	**CASE NO. 1:11-CV-0334-TWT**

INDIRECT PURCHASERS' OPPOSITION TO
PAR'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

I. INTRODUCTION

In July 2003, Par[1] sent Unimed,[2] the manufacturer of AndroGel, a paragraph IV certification letter explaining why its proposed generic product did not infringe Unimed's '894 patent for a 1% testosterone gel. The '894 patent did not, in fact, cover Par's product. It didn't even cover AndroGel. Due to "a series of colossal blunders," the patent only covered testosterone gel formulations that contained 50 to 250 times more sodium hydroxide than AndroGel (and Par's product).[3] And even if the '894 patent had covered AndroGel and Par's product, the patent would be invalid as a result of inadequate written description and earlier public use of AndroGel.

Unimed was faced with a choice. It could act within the law, admit that the '894 patent did not cover Par's product, and suffer significantly reduced sales from the entry of less expensive generic products. Or it could act unlawfully, pretend its '894 patent covered Par's product, and delay generic entry by filing a baseless patent infringement suit against Par. Unimed chose the latter, and filed a frivolous lawsuit.

Unimed then compounded its mistakes. Seeking an after-the-fact fix to its patent problems, Unimed obtained a certificate of correction ("COC") by misrepresenting and disguising as "typographical" a fundamental change to the patent – the percentage of sodium hydroxide. Never mind that this deception was the only way Unimed could

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[1] "Par" is used throughout in reference to Defendant's Par Pharmaceuticals Inc. and Paddock Pharmaceuticals Inc.

[2] "Unimed" is used throughout in reference to Defendant Abbott Pharmaceuticals Inc. and/or Solvay Pharmaceuticals Inc.

[3] *See* Plaintiffs' Statement of Additional Material Facts ("SAMF") at ¶¶ 112-113; Ex. 074, Paddock Mem. in Supp. of its Mot. for Partial S. J., at 5.

achieve this after-the-fact amendment to the patent; since the *Par* lawsuit had already been filed against Par, the fraud-induced fix would not apply to Par anyway.

Par correctly responded that Unimed's infringement claims were "baseless," "illogic[al]," and "plainly not. . . reasonable."[4] It claimed the late-issued COC was both invalid and inapplicable in the suit against Par. Par's experts agreed. Par even claimed Unimed's suit to be so baseless and "exceptional" that it sought an award of attorneys' fees.[5] And Par believed the likelihood of success to be so high it moved for partial summary judgment. But before the Unimed infringement action was determined on the merits, Unimed and Par settled. [redacted]

In what can only charitably be described as a remarkable act of chutzpah, Par now moves for summary judgment saying Unimed's lawsuit against it had merit. [redacted] Par now claims, (1) Par could have done an inadequate job of defending itself at trial, (2) a jury could have believed Unimed's "facially plausible" though deeply flawed expert testimony, and (3) Par was not "virtually assured of winning."

But Par had it right the first time. Unimed's suit was, in fact, a sham.

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[4] Ex. 071, Paddock Mem. in Supp. of its Mot. for Partial S.J., at 24, 30, 34.
[5] Ex. 166, Par's Answer at p. 8 (citing 35 U.S.C. § 285, allowing awards of attorneys' fees in exceptional cases where claims are objectively and subjectively baseless).
[6] Ex. 178, Project Tulip Presentation at 4407.

According to *PRE*,[7] the *Par* lawsuit is only immunized if Unimed had a realistic expectation of success on the merits. Par's motion rests on incorrect revisions of this legal standard. Par has not met, nor could it meet, the PRE standard because Unimed's suit was objectively baseless.[8]

II. FACTS

A. AndroGel

AndroGel is a 1% testosterone gel used to treat male hypogonadism.[9] AndroGel contains testosterone, isopropyl mystristate, alcohol, the gelling agent carbopol, and sodium hydroxide.[10] Sodium hydroxide, a base, neutralizes the formulation and allows carbopol molecules to unfurl.[11] This unfurling increases the viscosity of the product, creating the gel that gives "AndroGel" its name.[12] Without sodium hydroxide, there is no gel. Without a gel, the product would not adhere to the skin and patients would not receive the proper amount of testosterone.[13]

Unimed began conducting Androgel clinical trials in 1996.[14] In every phase, Unimed publically extolled the testings' successes. [redacted]

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[7] *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 62 (1993) ("*PRE*").
[8] Indirect Purchasers have joined Direct Purchaser's Motion for Summary Judgment filed contemporaneously.
[9] SAMF at ¶ 5.
[10] *Id.* at ¶ 43.
[11] *Id.* at ¶ 166.
[12] *Id.* at ¶¶ 164-168.
[13] *Id.* at ¶ 171.
[14] *Id.* at ¶¶ 29, 210, 224.

[redacted].[15] The FDA approved AndroGel in February 2000.[16]

B. The '894 patent

Usually, drug companies seek patent protection well before *applying* for FDA approval to market a new drug. But Unimed did not apply for the '894 patent until August 2000,[17] two months after AndroGel *entered the market* in June 2000.[18]

1. Claims 1-30

Claims 1-30 of the '894 patent describe formulations containing testosterone, isopropylmyristate, an alcohol, a gelling agent, and sodium hydroxide. "Sodium hydroxide" means pure sodium hydroxide.[19]

During prosecution of the application, Unimed realized it needed to describe a quantitative range for pure sodium hydroxide (because no quantity had been specified, and Unimed had already described the invention in terms of the pure sodium hydroxide, not some dilute form). However, Unimed's specification in the original patent application (1) did not refer to *any* range of sodium hydroxide, (2) did not refer to data points that would correspond to an upper or lower bound, (3) only referred to a single

[15] *Id.* at ¶¶ 204-209.
[16] *Id.* at ¶ 33.
[17] *Id.* at ¶ 37.
[18] *Id.* at ¶¶ 11, 34.
[19] *Id.* at ¶ 103.

data point ("4.72 g of 0.1N NaOH") specific to one embodiment of the invention (namely AndroGel).[20]

In an effort to support some form of a range, Unimed provided the PTO with a calculation of a single point that converted an amount of 0.1N sodium hydroxide solution into an amount of pure sodium hydroxide.[21] But Unimed botched the mathematical calculation and presented a range of 1-5% (or 1-3%) pure sodium hydroxide for claims 1-30. Unimed claimed that calculation showed AndroGel contained 1.8 grams of pure sodium hydroxide in 100 grams of gel – or, in other words, that AndroGel was comprised of 1.8% pure sodium hydroxide.[22] In fact, Unimed made a two decimal place error. AndroGel in fact contains only 0.018% pure sodium hydroxide.[23] Unimed had built its claimed sodium hydroxide ranges (1-5% and 1-3%) around the miscalculated 1.8% pure sodium hydroxide. The ranges above and below this single point were unsupported guesswork. As issued, claims 1-30 refer to an amount of pure sodium hydroxide about 50 to 250 times greater than the amount contained in AndroGel or Par's product.[24]

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[20] *Id.* at ¶¶ 181-188.
[21] *Id.* at ¶¶ 56-59. (Unimed provided the following calculation: "Note that 4.72g of 0.1N NaOH=about 1.8g NaOH in 100g of gel, or about 1.8%")
[22] *Id.* at ¶ 57.
[23] *Id.* at ¶ 59.
[24] *Id.* at ¶¶ 112-113.

2. Claims 31-40

Claim 31 is an independent claim that describes a formulation "consisting essentially of" testosterone, isopropylmyristate, an alcohol, and a gelling agent.[25] Claim 31 does not recite sodium hydroxide.[26] Claims 32 through 42 are dependent on Claim 31.[27]

C. Par's paragraph iv certification letter

Par's paragraph iv certification letter stated that the [redacted] [redacted][28]

D. The certificate of correction

Three weeks after Par filed its ANDA, Unimed tried to rewrite its patent to cover AndroGel and competing generics by applying for a COC, the only available method to achieve *nunc pro tunc* changes to a patent.[29] Unimed asked the PTO to insert the term "0.1N" (a phrasing for a specific concentration of a sodium hydroxide solution consisting of 95% water) before the phrase "sodium hydroxide" in claims 1-30. Unimed buried this substantive change among 18 requests to have to the PTO correct misspellings, remove a period, and add a hyphen.[30] Unimed told the PTO that the omission of "0.1N" was a good faith mistake, that the "proper language is contained

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[25] Ex. 001, '894 patent, col. 52, ll. 5-15.
[26] SAMF at ¶ 66.
[27] *Id.* at ¶ 143.
[28] *Id.* at ¶¶ 70, 95.
[29] *Id.* at ¶ 78.
[30] *Id.* at ¶¶ 79-80.

throughout the specification" (citing the only reference to sodium hydroxide in the entire specification)[31] and that the change "would not constitute new matter" or "require reexamination by the PTO."[32]

In the meantime, Unimed filed suit against Par with the uncorrected patent in August 2003. Six months later, in December 2003 the PTO issued the COC.[33]

III. THE SUMMARY JUDGMENT STANDARD[34]

Summary judgment may only be granted if a reasonable fact finder could not find for plaintiffs when viewing the evidence and making all reasonable inferences in

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[31] *Id.* at ¶¶ 81-82.
[32] *Id.* at ¶ 81.
[33] *Id.* at ¶ 83.
[34] Violations of antitrust laws are assessed by the preponderance-of-the-evidence standard. *Litton Systems, Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 813 (2d Cir. 1983); *see also Grogan v. Garner*, 498 U.S. 279, 286 (1991) (preponderance of the evidence is the presumptive standard); *Herman & MacLean v. Huddleston*, 459 U.S. 375, 389-90 (1983). But at summary judgment, there is little practical distinction between clear-and-convincing and preponderance-of-the-evidence. *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 270-71 (U.S. 1986) (J. Brennan, J. Rehnquist, and J. Berger dissenting). Here, plaintiffs have provided enough factual support to prove their case by either standard. *See, e.g., In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 311 n.12 (E.D. Pa. 2011) ("I need not consider the distinction between the two standards here, where Plaintiffs' evidence, construed in the light most favorable to them, is sufficient to survive summary judgment under either standard.").

plaintiffs' favor.[35] Par bears the burden of showing a lack of genuine issues of material fact.[36]

Here, summary judgment is set against the backdrop of *Noerr-Pennington* qualified immunity. A litigant enjoys immunity only if a "reasonable litigant could realistically expect to secure favorable relief."[37] A patentee in an infringement suit only has immunity if he "could realistically expect success on the merits" of his suit – that is, if the suit was "reasonably calculated" to elicit a "favorable outcome" or "favorable relief."[38]

A court cannot determine whether a reasonable petitioner could realistically expect to secure favorable relief *as a matter of law* when the parties dispute material predicate facts.[39] Material predicate facts include any facts tending to prove or disprove

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[35] Fed. R. Civ. P. 56(c); *U.S. v. Four Parcels of Real Property*, 941 F.2d 1428, 1437 (11th Cir. 1991) ("A factual dispute is genuine 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'"), quoting *Anderson*, 477 U.S. at 251-252; *Bannum, Inc. v. Ft. Lauderdale*, 901 F.2d 989, 996 (11th Cir. 1990) ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.").

[36] *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *see also Sweeney v. Boyd*, 2011 U.S. Dist. LEXIS 28943, at *2-3 (M.D. Ala. Feb. 2, 2011) (granting summary judgment only after moving party met burden to show absence of dispute as to material facts and non-moving party could not establish any such dispute); *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991) (summary judgment reversed for error of placing burden on non-moving party).

[37] *PRE* at 62.

[38] *Id. at* 60, 62. *PRE* also require antitrust plaintiffs to prove the baseless lawsuit was motivated by malevolent subjective intent. Par does not argue that Unimed acted in good faith.

[39] *Id.* at 63 (only when "there is no dispute over the predicate facts" may a court decide "probable cause as a matter of law."); *see also Breckenridge Pharm., Inc. v. Metabolite*

the objective baselessness of defendants' petitions, and are not limited to the facts contained in the records of the underlying patent infringement litigation.[40] Courts in pharmaceutical antitrust cases hold that when the parties dispute predicate facts about the underlying (sham) petitioning, objective baselessness must be reserved for trial.[41]

Lab., Inc., 444 F.3d 1356, 1369 (Fed. Cir. 2006) (vacating grant of summary judgment due to genuine issues of material fact concerning whether statements were objectively baseless).

[40] *See, e.g.*, *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d at 360-61 ("the relevant 'predicate facts' are not only the facts determined in the prior lawsuit, but also those facts tending to prove or disprove the existence of probable cause").

[41] *See*, *In re Tricor Antitrust Litig.*, 580 F. Supp. 2d 345, 362 (D. Del. 2008) (denying summary judgment because "a jury could find defendants' infringement allegations objectively baseless, such as to render the capsule litigation a sham."); *In re Relafen Antitrust Litig.* 346 F. Supp. 2d at 364 (the court ruled that the disputed "state of SmithKline's knowledge at the time of filing" was relevant to assessing objective baselessness, denied summary judgment "in light of the disputed factual issues," and noted it was his "duty" to submit these disputed issues to a jury); *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 U.S. Dist. LEXIS 77475, at *97 (D.N.J. Aug. 28, 2009) (the court concluded "when the predicate facts of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law."); *La. Wholesale Drug Co. v. Sanofi-Aventis ("Arava")*, 2009 U.S. Dist. LEXIS 77206, at *17 n.4 (S.D.N.Y. Aug. 28, 2009) ("[b]ecause I found, at the summary judgment stage, that there were genuine issues pertaining to the 'predicate facts' surrounding the [petition], I declined to take the question of objective baselessness away from the jury before trial. . . . "); *Arava*, 2008 U.S. Dist. LEXIS 3611, at *17-18 (S.D.N.Y. Jan. 18, 2008) (denying summary judgment where "there are genuine issues of facts with respect to the Defendants' objective basis for filing the Petition."); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (the court noted the numerous disputed facts and concluded that "[t]he question whether a petition is a sham is generally a question of fact for the jury."); *In re Wellbutrin SR Antitrust Litig.*, 2010 U.S. Dist. LEXIS 90162, at *6-8 (E.D. Pa. Aug. 31, 2010) (refusing to reconsider its prior decision denying summary judgment on sham litigation claim because a jury could find that the patentee's suit was baseless).

IV. ARGUMENT

A. Unimed's *Par* lawsuit lacked any reasonable basis.

1. Original claims 1-30 did not cover Par's product.

No reasonable litigant would realistically expect to prove that Par's product infringed original claims 1-30 of the '894 patent. [redacted] [42] Unimed later admitted that Par's product did not infringe original claims 1-30 of the '894 patent.[43] Plaintiffs are entitled to summary judgment on this issue unless Par advances credible evidence that original claims 1-30 covered Par's product.

2. Proposed corrected claims 1-30 did not apply to Par's product.

No reasonable litigant would realistically expect to succeed on the merits of its infringement action by arguing that the later-issued COC applied to Par.

First, at the time that Solvay actually filed its suit, there *was no* COC. As this Court has already noted, "[t]he original '894 patent matters because '[antitrust] analysis should focus on what the litigant knew or reasonably could have known *at the time the suits were filed.*'"[44]

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[42] SAMF at ¶¶ 112-113.
[43] *See id.* at ¶ 95, 101-107, 112-113, 123.
[44] Ex. 165, Order of Feb. 22, 2010, p. 18 n.4 (emphasis added) (*citing In re Wellbutrin SR Antitrust Litig.*, No. Civ. A 04-5525, 2006 WL 616292, * 11 (E.D. Pa. Mar. 9, 2006).

Second, a COC does not apply to acts of alleged infringement that occurred before it issued.[45] Here, the alleged act of infringement – the filing of Par's 1% testosterone gel ANDA – occurred in May 2003.[46] The COC did not issue until December 2003, four months after Unimed sued Par for infringement.[47] Plaintiffs are entitled to summary judgment on this issue unless Par advances credible evidence that the CoC was valid and applied in the litigation against Par.

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[45] *Southwest Software v. Harlequin Inc.*, 226 F.3d 1280, 1294 (Fed. Cir. 2000); s*ee also Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1356 (Fed. Cir. 2003) ("For causes of action that arise before the correction becomes effective, the patent must be considered without the benefit of the certificate of correction.")

[46] SAMF at ¶ 68.

[47] Par cites *Central Admixture v. Gerald Buckberg*, 2006 WL 4448613, at *17 (N.D. Ala. Jan. 13, 2006), a case later vacated by the Federal Circuit, to suggest that Unimed may have had a "non frivolous" argument for "extending existing law or establishing new law." Par Br. at 11-12. *Central Admixture* is inapposite for several reasons. First, the objective reasonableness of the suits must be evaluated under the state of the law as it existed at the time the suits were filed, not years later. Ex. 165, Order of Feb. 22, 2010, p. 18 n.4 (emphasis added) (*citing In re Wellbutrin SR Antitrust Litig.*, No. Civ. A 04-5525, 2006 WL 616292, * 11 (E.D. Pa. Mar. 9, 2006). In this case, there is no dispute that no COC had issued at the time Unimed filed suit – and whatever the patent consequences of a later-issuing COC, they cannot possibly cure the antitrust defect of suing on a non-infringed patent. Secondly, in *Central Admixture*, the causes of action arose *after* the COC had issued. The facts of this case are akin to those of *Southwest Software* where both the cause of action accrued, and the litigation was filed, prior to the issuance of the COC. *Southwest Software*, 226 F.3d at 1293-94. In any event, *Central Admixuture* is not instructive. And in any case, "uncertainty in the law by itself . . . is not sufficient to create probable cause [to file a patent infringement suit]." *In re Wellbutrin SR Antritrust Litig.*, 2006 U.S. Dist. LEXIS 9687, *28 (E.D.Pa. Mar. 9, 2006). Even if *Central Admixture* were somehow applicable, it in no way justifies Unimed's suit against Par premised on Par's ANDA filing. Hatch Waxman does not require a branded manufacturer to file suit within 45 days or lose all rights to sue for infringement. Unimed could have sued Par after the COC issued, assuming the COC was valid (which it was not) and when and if there was some later act of infringement by Par. Of course, if it waited Unimed would lose the advantageous 30 month automatic stay it desperately sought.

3. Corrected claims 1-30 are invalid.

Finally, correct claims 1-30 were invalid. COCs can only be used to correct mistakes (1) of a clerical nature, (2) of a typographical nature, or (3) of minor character.[48] Clerical or typographical mistakes include "obvious" and "immediately apparent" misspellings.[49] A COC cannot be used to make changes that would (1) constitute new matter or (2) require reexamination.[50] If a patentee cannot properly correct a mistake with a COC, the only recourse is to admit that the original patent was either inoperative or invalid and seek reissuance of the patent;[51] this restarts the patent application process, and reissued patents are only effective from the date of reissuance, not the priority date of the original patent.[52] A reissued '894 patent that actually covered AndroGel would not have prevented Par from coming to market.

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[48] 35 U.S.C. § 255

[49] *Superior Fireplace Co. v. Majestic Products Co.*, 60 U.S.P.Q.2d 1668, 1676 (Fed. Cir. 2001).

[50] *Id.* (A broadening correction of a clerical or typographical error can only be allowed "where it is clearly evident from the specification, drawings, and prosecution history, how the error should be appropriately corrected."); *In re Arnott*, 1991 Commr. Pat. LEXIS 10, at *13 (Comm'r Pat. & Trademarks May 22, 1991) ("Even if the mistake is of the proper type, a certificate of correction cannot issue if the proposed correction involves changes which would constitute new matter or require reexamination."); *Superior Fireplace Co. v. Majestic Products Co.*, 60 U.S.P.Q.2d 1668, 1679 (Fed. Cir. 2001)

[51] 37 C.F.R. 1.175; 21 C.F.R. 1.176(a). A patent holder could seek reexamination of the patent, but reexamination raises the possibility that the PTO would find the patent invalid, which would force reissuance proceedings.

[52] *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 491 (U.S. 1935) ("the re-issued patent, with respect to the amended claim, speaks from the date of

Unimed's stated range for pure sodium was not a clerical error or typo that could be resolved with a certificate of correction. The range of solid (pure) sodium hydroxide was based on a mathematical error (1.8% instead of 0.018%). A math mistake should be corrected by doing the math the right way. Here, that meant changing the range of from "1% to 5%" to a range of "0.01% to 0.05%" (or 0.01% to 0.03%) for pure sodium hydroxide. But doing so would have tipped off the PTO to the magnitude of Unimed's mistake; a major change in the quantity of a key component. So Unimed tried to disguise its error as a minor typo of the sort that could be corrected with a COC. Unimed left the incorrect range of pure sodium hydroxide intact, and instead inserted "0.1N" before "sodium hydroxide" to make it look like the range was always meant to refer to a weak solution of sodium hydroxide elsewhere specified in the patent. But this was simply false – Unimed had never intended to provide a range for a specific dilute sodium hydroxide; it had attempted a range for pure sodium hydroxide. Nevertheless, Unimed's subterfuge, coupled with camouflaging the change with numerous real clerical mistakes, successfully tricked the PTO into issuing the COC.

Unimed later admitted that the COC "correction" significantly altered the scope of (or broadened) its claims.[53] But broadening corrections can only be made through a COC if "it is clearly evident from the specification, drawings, and prosecution history,

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re-issue"); *Peck v. Collins*, 103 U.S. 660, 664 (U.S. 1881) ("no damages can be recovered for any acts of infringement committed prior to the reissue").

[53] SAMF at ¶ 123.

how the error should be appropriately corrected."[54] As Unimed's experts conceded, if the math error were corrected by specifying a dilute concentration of sodium solution in place of the pure sodium (instead of correcting the ranges), then the alleged "typo" could be corrected in any number of ways, including by changing the range, changing the molarity, or changing both the range and the molarity:

4.72 g of 0.1N NaOH = 0.018g NaOH in 100g gel
0.787 g of 0.6 N NaOH = 0.018g NaOH in 100g gel
9.44 g of 0.05N NaOH = 0.018g NaOH in 100g gel

And even as corrected, claim 9 (now reciting 1-3% 0.1N sodium hydroxide) did not cover Androgel or Par's product.

As Par argued during the infringement action, "[t]here is absolutely no basis whatsoever in the intrinsic record for Unimed's conclusory assertion that somehow 0.1N was mistakenly omitted from the claims."[55] Any reasonable manufacturer would conclude that, under the stark light of later patent infringement litigation, this subterfuge would be uncovered and the COC would not hold up. Plaintiffs are entitled to summary judgment on this issue unless Par advances credible evidence that the COC and corrected claims 1-30 are valid.

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[54] *Superior Fireplace Co. v. Majestic Products Co.*, 60 U.S.P.Q.2d 1668, 1676 (Fed. Cir. 2001).
[55] SAMF at ¶ 136.

4. Claims 31-42 did not cover Par's product.

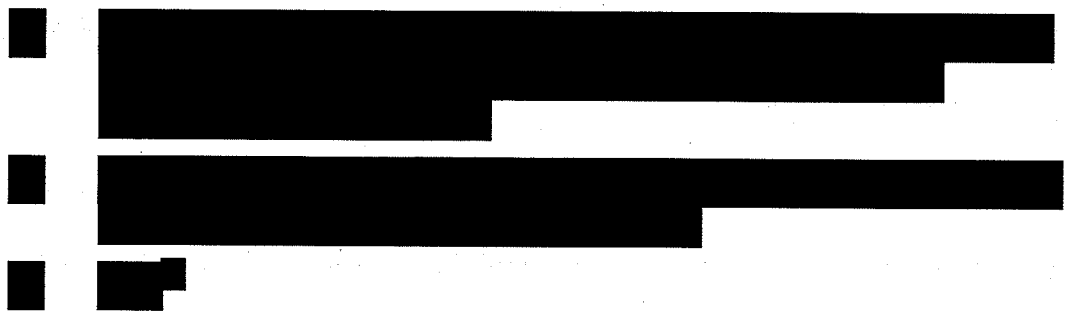
The evidence shows no reasonable litigant would realistically expect to prove Par's product infringed claims 31-42 of the '894 patent. Claim 31 does not identify sodium hydroxide as a component of the claimed invention.

The phrase "consisting essentially of" limits the scope of a claim to the specific materials or steps listed "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention[56] – the claim only covers formulations that include the listed materials and other non-material components. "[T]here is no infringement where the accused product contains additional unclaimed ingredients that materially affect the basic and novel properties of the invention."[57]

Par's product could not possibly infringe claims 31- 42 because it contained sodium hydroxide.[58] Sodium hydroxide is essential for the formation of a gel.[59]

[redacted]

[56] *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).
[57] *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006); *see also AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984).
[58] Unimed arguments in response were deeply flawed. Plaintiffs will address those arguments in responding to Unimed's motion for summary judgment.
[59] SAMF at ¶ 142-178.
[60] *Id.* at ¶¶ 50, 164-169.



Any reasonable person skilled in the art would conclude (i) sodium hydroxide impacts the basic and novel properties of the invention, and (ii) claims 31-42 omit sodium hydroxide and thus do not cover formulations that include sodium hydroxide. Plaintiffs are entitled to summary judgment on this issue unless Par advances credible evidence that claims 31-42 covered Par's product.

5. All claims of the '894 patent were invalid.

No reasonable litigant would realistically expect to succeed in an infringement action against Par because if the '894 patent covers Androgel or Par's product (a big if), then all claims in the '894 patent are invalid.

a. The patent specification does not support the sodium hydroxide ranges in claims 1-30.

Unimed could not reasonably expect that a court would find claims containing unsupported numerical ranges of sodium hydroxide to be valid.

Patent law and formulation science provide that applicants cannot add or change a numerical range during prosecution of a patent unless the patent application disclosed examples supporting the lower and upper bounds of that range.[62] A person of ordinary

[61] SAMF at ¶ 160; Weiner Tr. at p. 245, ln 3-13.
[62] *In Re Lucach et al.*, 169 USPQ 759, 797 (CCPA 1971).

skill in the art would interpret such ranges to mean that the applicant had data points supporting those ranges.[63]

The patent specification Unimed submitted with its original patent application did not refer to *any* range of sodium hydroxide, did not refer to data points that corresponded to the upper or lower bounds of the 1-5% range, and only contained a single data point ("4.72 g of 0.1N NaOH") that is equivalent to 0.018% sodium hydroxide.[64] Unimed admits that the single data point falls outside of the 1-5% range claimed in the uncorrected patent.[65] The patent simply guesses about a range around a single given point. No reasonable person skilled in the art would realistically expect the rangeless '894 patent specification to support the guessing found in the claims. Plaintiffs are entitled to summary judgment on this issue unless Par advances credible evidence that the ranges of sodium hydroxide in claims 1-30 are supported by the patent specification.

b. Prior public use of AndroGel invalidates the patent.[66]

Unimed's suit against Par was also destined to fail by reason of the prior public use doctrine. If Unimed somehow managed to get the '894 patent construed to cover the 1% testosterone gel product, Androgel had been in public use and reduced to

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[63] SAMF at ¶¶ 184, 186-187, 194.
[64] *Id.* at ¶¶ 181-188.
[65] *Id.* at ¶¶ 112-113. Unimed's expert countered that one skilled in the art would infer a range of sodium hydroxide based on the range of carbomer (gelling agent) disclosed in the specification. Par contested the expert's testimony. Plaintiffs will address Unimed's flawed argument in responding to Unimed's motion for summary judgment.
[66] The '894 patent was also invalid because of Unimed's earlier offer to sell AndroGel. But as Par has not raised this issue, we do not address it in detail.

practice for over a year before the patent was applied for, making the invention unpatentable.

An invention cannot be patented if it was used publicly and reduced to practice more than a year before the inventor applied for patent protection.[67] Public use includes any use of the claimed invention by someone who is under no obligation of secrecy to the inventor.[68] Public use of high-level aspects of the product is enough to place the claimed features of the product in the public.[69] An invention is reduced to practice when it is "understood to work for its intended purpose."[70]

AndroGel was reduced to practice and used publicly well over a year before Unimed applied for the '894 patent.[71] Unimed sought FDA approval of AndroGel one year and four months before applying for a patent. Participants in Unimed's clinical trials were not obligated to keep information about AndroGel secret.[72] Unimed was only able to convince the PTO that AndroGel clinical trials did not constitute "public use" by misrepresenting that the clinical studies were secret and confidential.[73] Unimed

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[67] 35 U.S.C. § 102(b) (the "on-sale bar"); *Pfaff v. Wells Elecs*, 525 U.S. 55, 67 (U.S. 1998).
[68] *Vanmoor v. Wal-Mart Stores, Inc.*, 1998 U.S. Dist. LEXIS 22694, at *10 (S.D. Fla. Dec. 15, 1998) ("An invention is considered 'in public use' where there is any use of the claimed invention by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor.)
[69] *Lockwood v. American Airlines*, 107 F.3d 1565, 1570 (Fed. Cir. 1997).
[70] Par Br. at 19 (citing *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1426 (Fed. Cir. 1996).
[71] SAMF at ¶¶ 202-239.
[72] *Id.* at ¶ 203.
[73] *Id.* at ¶¶ 202-209.

failed to mention that it had repeatedly publicly bragged about the success of its 1% testosterone gel clinical trials.[74] Unimed also distributed thousands of packets of AndroGel placebos over a year before it sought patent protection. Though the placebos did not contain testosterone, they were touted as samples of a 1% testosterone gel and displayed publically on television.[75]

No person skilled in the art would realisticallyexpect to avoid the conclusion that Androgel's public use a year before filing the patent application invalidated the '894 patent if the patent covered Androgel. At a minimum, the parties dispute factual matters regarding Unimed's public use of AndroGel, the critical date of its use, and whether and when AndroGel was reduced to practice. The disputes preclude summary judgment.

B. Par's sham litigation standard is wrong.

1. Par's "virtual assurance" argument lacks merit.

PRE does not refer to "open and shut" cases.[76] It does not use the phrase "virtually assured of victory."[77] It does not speak of "assurances."[78] *PRE* does not, as Par would have the Court believe, immunize all cases where there is some glimmer of

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[74] *Id.* at ¶¶ 205, 214-219.
[75] *Id.* at ¶ 206-209

[76] Par Br. at 1 ("the threshold inquiry here, under [*PRE*] is strictly whether the merits of the underlying patent case were ***open-and-shut***.") (emphasis in original); *id.* at 6.
[77] Par Br. at 6 ("the Private Plaintiffs cannot muster clear and convincing evidence that … [Unimed] was virtually assured of losing an Par/Paddock was virtually assured of winning;" "objectively as so open-and-shut as to support a finding that either side was virtually assured of success or failure"); *see also id.* at 1, 11, 12, 14, 16, 18, 20, 21, 23, 24.
[78] Par Br. at 23 ("Par/Paddock could have no assurance of success), 24 (referring to an "assured outcome" and being "assured of success").

an outside chance that the defendant could lose.[79] A litigant is only immunized if its lawsuit is "reasonably calculated" to elicit a "favorable outcome" or "favorable relief." *PRE* does, sometimes, use the word "chance," but that chance must be "reasonable" and "realistic."[80] To determine that a lawsuit can only be a sham if it is *literally impossible* for the plaintiff to win ignores *PRE* and eviscerates the entire notion of *objective* baselessness.[81]

2. Par's "we thought we might lose" argument lacks merit.

Par suggests (without factual support) that it had a subjective belief it might lose.[82] Again, this is not the test.

Putting aside the hypocrisy behind these statements (after all, in the underlying suit Par argued Unimed's lawsuit warranted sanctions for its frivolity),[83] the objective reasonableness of Unimed's positions must be assessed against the law and evidence, not against Par's speculation that, after all, a jury could have accepted defendant's "facially plausible" but deeply flawed expert testimony over Par's well supported

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[79] In fact, *PRE* and its progeny make clear that a mere scintilla of a chance that the plaintiff could theoretically prevail on some small portion of their lawsuit is not enough to immunize its antitrust violations: "[i]t might not be objectively reasonable to bring a lawsuit just because some form of success on the merits – no matter how insignificant – could be expected." *PRE* at 68.

[80] *PRE*, 508 U.S. at 62-63 (requiring a "reasonable belief that there is a chance that a claim may be held valid upon adjudication")); *id.* at 62 (reasonable litigant must "realistically expect to secure favorable relief").

[81] Par argues that Unimed's lawsuit was objectively reasonable because Par was not "virtually assured of success … at trial." *See, e.g.*, Par Br. at 21. But *PRE* asks whether it a reasonable person would realistically expect success on the merits, not whether the accused infringer was sure it would win at trial.

[82] Par Br. at 11-13.

[83] Ex. 166, Par's Answer at 8.

arguments challenging that testimony. "It is not what the parties think of the merits of their positions that matters; it is whether there are, in fact, sufficient objective bases for the positions taken."[84]

C. Par's summary judgment standard is wrong.

1. Par's "inverted burden" argument lacks merit.

On the one hand, Par appears to concede that the existence of disputed issues of fact in the underlying patent litigation required that case to go to a jury. Yet, in this case Par inverts the summary judgment standard, arguing that disputed issues of fact require granting summary judgment unless *plaintiffs* can prove there are no disputed issues of fact.[85]

This is not the standard. At summary judgment, the court must determine whether there are "any genuine factual issues that properly can be resolved only by a finder of fact."[86] Similar pharmaceutical antitrust cases reject this inverted burden argument and hold that disputed issues of fact as to objective reasonableness must be resolved at trial.[87] This Court should do the same.

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[84] *In re Buspirone Patent Litig.*, 185 F.Supp.2d 366, 375 (S.D.N.Y. 2002); *see also In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1380 n.4 ("antitrust analysis should focus on what the litigant knew or reasonably could have known at the time the suits were filed") (citation omitted).

[85] *Par* Br. at 24.

[86] *Anderson,* 477 U.S. at 225.

[87] *In re Tricor Antitrust Litig.*, 580 F. Supp. 2d at 362 (denying summary judgment as to all of the *PRE* claims because the plaintiffs had adduced sufficient facts of objective baselessness to counter the defendant's expert's opinion); *La. Wholesale Drug Co., Inc. v. Sanofi-Aventis* ("*Arava*"), 2008 U.S. Dist. LEXIS 3611,*17-18 (S.D.N.Y. Jan. 18, 2008) (denying summary judgment where "there are genuine issues of facts with respect

2. Par's "might have gone to trial" argument lacks merit.

Par argues it is entitled to judgment because the underlying patent suit was "indisputably" going to trial.[88]

First, this is factually untrue. Trial was not guaranteed. At the time the parties settled, every claim of the '894 patent was subject to a potentially case-dispositive pre-trial motion.[89] Even if this Court declined to decide whether claims 31-42 excluded sodium hydroxide, as Par urged[90] the May 25, 2005 scheduling order contemplated additional summary judgment motions after claims construction.[91] And when Par asked the Court to construe the "consisting essentially of" language when "assessing infringement," Par was referring to post-*Markman* summary judgment briefing.[92] Par did not ask the Court to defer the issue until trial.[93]

Second, *heading* to trial does not mean the patentee has a realistic likelihood of *winning* at trial. In *In re Tricor Antitrust Litig.*, the court refused to grant Abbott

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to the Defendants' objective basis for filing the Petition."); *In re Relafen*, 346 F. Supp. 2d at 360-361 ("[w]hen [facts tending to prove or disprove the existence of probable cause] are in dispute, it becomes the duty of the trial court to submit the question to the jury.") (internal citations and quotations omitted); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 317 (E.D. Pa. 2011) (denying summary judgment "because genuine issues of fact remain as to whether GSK's conduct was objectively baseless"); *In re Wellbutrin SR*, 2010 U.S. Dist. LEXIS at *8 (denying summary judgment because plaintiffs have presented evidence sufficient to create material issues of fact).

[88] Par Br. at 5-6, 9.

[89] Ex. 071, Par Mem. in Supp. of its Motion for Partial S.J.; Ex. 074, Par Mem. in Supp. of its Motion for Partial S.J.; Ex. 076, Watson Mem. in Supp. of its Motion for Partial S.J.; Ex. 167, Watson Mem. in Supp. of its Motion for Partial S.J.

[90] Par Br. at 3.

[91] Ex. 066, Court Order.

[92] Par Br. at 17, 18 n.22.

[93] Ex. 069, Par Opp. Claim Constr. Brief at 34.

summary judgment despite the fact the patent case had been headed to trial, because a settlement "deprived the court of the opportunity to flesh out the merits of the remainder of its claims." [94] The court refused to "afford [Abbott] the benefit of the doubt that its claims were reasonable."[95] As in *Tricor*, this Court should not give defendants the benefit of the doubt that Unimed's claims were reasonable.

In every case cited by Par, the claim was held not to be objectively baseless because a court had fleshed out the merits of the claim and held it survived summary judgment.[96] None of Unimed's claims *survived* summary judgment because settlement prevented a substantive ruling. And even surviving summary judgment does not render claims immune from suit as a matter of law.[97]

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[94] *Tricor*, 580 F. Supp. 2d. at 365.

[95] *Id.*

[96] *See* Par Br. at 5, citing *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1370 (Fed. Cir. 2004) (the patent holder's "claims *survived* [alleged infringer's] motion for summary judgment") (emphasis added); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (the claim at issue "*survived* a motion for summary judgment") (emphasis added); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1414 (Fed. Cir. 1987) ("the patent holder had *survived* summary judgment") (emphasis added).*See also* SJ Br. at 9 n.12, citing *Metris U.S.A., Inc. v. Faro Techs., Inc.*, 2011 U.S. Dist. LEXIS 105865, at * 32 (D. Mass. Sept. 19, 2011) (the claims "have at least enough merit to withstand summary judgment"); *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. supp. 2d 221, 224 (S.D.N.Y.) (determinations allowed claims "to proceed beyond summary judgment"); *ADT Security Sys., Inc. v. Guerra*, No. 3:95-cv-1051 1997 WL 114784, at *2 (D. Conn. Mar. 4, 1997) (the court "concluded that [defendant's] claims are worthy of presentation to the trier of fact"); *Harris Custom Builders, Inc. v. Hoffmeyer*, 834 F. Supp. 256, 261-262 (N.D. Ill. 1993 (discussing when a claim "is well enough grounded, factually and legally, to survive" summary judgment).

[97] Courts have repeatedly recognized that mere survival of summary judgment does not preclude a finding that the litigation was "baseless." *See, e.g., FilmTec Corp. v.*

3. Par's "Unimed hired experts" argument lacks merit.

Par maintains Unimed had "some chance" of winning because it hired "qualified" experts who submitted "facially plausible" testimony in support of its positions.[98] Again, this sidesteps the proper analysis required by *PRE*.

First, the relevant question under *PRE* is whether Unimed had a realistic likelihood of prevailing; that, in part, depends on the plausibility of what its experts *said*, not that they simply *existed*. Petitioners in the *Wellbutrin*, *Arava*, *Tricor,* and *Relafen* cases submitted testimony from "qualified" experts, yet the sham issue still fell to the jury because of what the experts said (or did not say). The Court should decline Par's invitation to create a potted-plant-as-expert rule.[99]

Second, each of Par's examples of "facially plausible" or "intuitively plausible" Unimed expert opinions only point to half the issue at play. For example, assuming *arguendo* as a theoretical matter that it is "facially plausible" to consider the omission the "0.1N" to be a "clerical mistake" under some circumstances, here the facts show that Unimed specifically intended to use a concentration of pure (not dilute, e.g., 0.1N)

Hydronautics, 67 F.3d 931, 937 (Fed. Cir. 1995) (explaining that "a preliminary success on the merits does not necessarily preclude a court from concluding that litigation was baseless"); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d at 362-65 (surviving summary judgment does not prove as a matter of law that the case was not objectively baseless); *Warner-Lambert Co. v. Purepac Pharm. Co.*, 2000 WL 34213890 at *5-6 (D.N.J. Dec. 22, 2000) (rejecting argument that "as a matter of law, a patent infringement suit which survives summary judgment cannot be considered 'objectively baseless'"); *see also* Hovenkamp IP and Antitrust Law § 11.3b2 ("the mere fact that an infringement lawsuit survives summary judgment does not render it a non-sham.").

[98] Par Br. at 13, 16, 25.

[99] *See e.g.*, Par Br. at 6, 25.

sodium hydroxide. As a result, it was objectively unreasonable for an expert to conclude that Unimed's failure to specify a diluted solution was a clerical mistake when in fact Unimed meant to specify an amount of the pure component.[100]

Third, Par previously claimed Unimed's expert's positions were "nonsense and contradicted by the plain text of the amendment" and "improper and demonstrably false."[101] And Par claimed Unimed was continuing to "pull the wool over the Court's eyes on this issue."[102]

V. CONCLUSION

No reasonable pharmaceutical manufacturer could conclude that Unimed had a realistic likelihood of prevailing on the merits and proving Par infringed the '894 patent. Par's motion should be denied.

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[100] SAMF at ¶¶ 53-62.
[101] Ex. 075, Par Reply Mem. in Further Supp. of its Mot. for Partial S. J., at 7, 9.
[102] *Id.* at 12.

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CERTIFICATE OF SERVICE AND TYPE

Pursuant to Local Rule 7.1D, the undersigned counsel for End-Payor Class Plaintiffs hereby certifies that the foregoing has been prepared with a font size and point selection (Times New Roman, 14 pt.) which was approved by the Court, and that on this 21st day of February, 2012, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to counsel of record.

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